

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Display Date	10/27/00
Publication Date	10/27/00
Certifier	<i>[Signature]</i>

Food and Drug Administration

21 CFR Part 172

[Docket No. 92F-0305]

**Food Additives Permitted for Direct Addition to Food for Human Consumption;
Polydextrose**

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of polydextrose as a bulking agent, texturizer, or both in table spreads. This action is in response to a petition filed by Pfizer, Inc.

DATES: This rule is effective *[insert date of publication in the Federal Register]*. Submit written objections and requests for a hearing by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Rosalie M. Angeles, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-418-3107.

SUPPLEMENTARY INFORMATION:

I. Introduction

In a notice published in the **Federal Register** of August 24, 1992 (57 FR 38311), FDA announced that a food additive petition (FAP 2A4332) had been filed by Pfizer, Inc., 235 East

42d St., New York, NY 10017-5755. Pfizer, Inc., subsequently announced the sale of the Pfizer Food Science Group and the transfer of the petition to Cultor Food Science, Inc., 430 Saw Mill River Rd., Ardsley, NY 10502. Recently, the petitioner announced a name change from Cultor Food Science, Inc., to Danisco Cultor America, Inc. (Danisco), to reflect the acquisition of the company by Danisco. The petition proposed to amend the food additive regulations in § 172.841 *Polydextrose* (21 CFR 172.841) to provide for the safe use of polydextrose as a bulking agent, texturizer, or both in tablespreads.

Polydextrose is intended to replace fully caloric ingredients and to produce reduced- or lower calorie and/or lower-fat tablespreads. The proposed use level of polydextrose in tablespreads is 5 to 12 percent with the weighted mean use level estimated to be 8.5 percent. The petitioner contends that this use level makes possible the formulation of lower-calorie tablespreads that compare favorably with prototypes that contain no polydextrose. The petitioner submitted data to substantiate this claim and to demonstrate that the use of polydextrose in tablespreads is technologically self-limiting (Ref. 1).

II. Conclusions

FDA estimated that the mean consumption of polydextrose from the proposed use in tablespread is 0.7 gram per person per day (g/p/d). The agency considers this consumption insignificant compared to the estimated cumulative intake of polydextrose of 17.5 g/p/d from all currently regulated uses of the additive. Therefore, FDA concludes that there will be a negligible increase in dietary exposure to polydextrose from the issuance of this amendment to the regulation (Ref. 2).

FDA has evaluated data in the petition and other relevant material in its files. Based on this information, the agency concludes that: (1) The proposed food additive use is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) the regulation in § 172.841 should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

On June 1, 1998, the President directed all Federal agencies to use “plain language” in all new documents. In compliance with this directive, FDA has drafted its amendment to § 172.841 using the principles of “plain language” set forth by the President. In amending the regulation, the agency is also making an editorial change by alphabetizing the list of regulated uses of polydextrose.

III. Environmental Impact

In the notice of filing, FDA gave interested parties an opportunity to submit comments on the petitioner’s environmental assessment. The agency received no comments in response to that notice.

The agency has carefully considered the potential environmental effects of this rule. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency’s finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

IV. Paperwork Reduction Act of 1995

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

V. Objections

Any person who will be adversely affected by this regulation may at any time file with the Dockets Management Branch (address above) written objections by [*insert date 30 days after date of publication in the Federal Register*]. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents are to be submitted and are to be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

VI. Reference

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Memorandum dated December 2, 1992, from the Division of Product Manufacture and Use to the Division of Petition Control, "FAP 2A4332: Pfizer, Inc., Polydextrose in Tablespreads, Technologically Self-limiting Level, Submission of 11-12-92."

2. Memorandum dated September 30, 1992, from the Division of Product Manufacture and Use to the Division of Petition Control, "FAP 2A4332 (MATS #658): Pfizer, Inc., Polydextrose as a Bulking Agent/Texturizer in Tablespreads, Submission of 6-22-92."

List of Subjects in 21 CFR Part 172

Food additives, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 172 is amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 348, 371, 379e.

2. Section 172.841 is amended by revising paragraph (c) to read as follows:

§ 172.841 Polydextrose.

* * * * *

(c) Polydextrose is used in accordance with current good manufacturing practice as a bulking agent, formulation aid, humectant, and texturizer in the following foods when standards of identity established under section 401 of the act do not preclude such use:

- (1) Baked goods and baking mixes (restricted to fruit, custard, and pudding-filled pies; cakes; cookies; and similar baked products);
- (2) Chewing gum;
- (3) Confections and frostings; dressings for salads;
- (4) Film coatings on single and multiple vitamin and mineral supplement tablets;
- (5) Frozen dairy desserts and mixes;
- (6) Fruit spreads;
- (7) Gelatins, puddings and fillings;
- (8) Hard and soft candy;
- (9) Peanut spread;

(10) Sweet sauces, toppings, and syrups; and

(11) Table spreads.

* * * * *

Dated: 10/20/00
October 20, 2000

L. Robert Lake

L. Robert Lake,
Director of Regulations and Policy,
Center for Food Safety and Applied Nutrition.

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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